05 - 29 - 07

PAC
IFW

Attorney's Docket No.: 17109-002001 / 911

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Manuel Vega *et al.* Art Unit : 1631
Serial No. : 10/022,249 Examiner : Lin, Jerry
Filed : December 17, 2001 Customer No.: 20985
Conf No. : 7196
Title : **HIGH THROUGHPUT DIRECTED EVOLUTION BY RATIONAL MUTAGENESIS**

MAIL STOP PETITIONS
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

TRANSMITTAL LETTER

Dear Sir:

Transmitted herewith are a Petition pursuant to 37 C.F.R. §1.181 for reconsideration and removal of the finality of the Office Action, mailed May 9, 2007; a check for $200 for the requisite petition fee; and a return postcard in connection with the above-captioned patent application. If a Petition for extension of time is needed, this paper is to be considered such Petition.

☒ The Commissioner is hereby authorized to charge any fee, including that submitted herewith if the attached check(s) is in the wrong amount or otherwise improper or missing, that may be due in connection with this and the attached papers, or with this application during its entire pendency or to credit any overpayment to Deposit Account No. 06-1050. A duplicate of this sheet is enclosed.

Respectfully submitted,
Fish & Richardson P.C.

Stephanie Seidman
Reg. No. 33,779

Attorney Docket No. 17109-002001 / 911
Address all correspondence to: 20985
Stephanie Seidman
Fish & Richardson P.C.
12390 El Camino Real
San Diego, California 92130
Telephone: (858) 678-5070
Facsimile: (202) 626-7796
email: seidman@fr.com

CERTIFICATE OF MAILING BY "EXPRESS MAIL"
"Express Mail" Mailing Label Number EV 740125484 US
Date of Deposit: **May 25, 2007**

I hereby certify that this paper is being deposited with the United States Postal "Express Mail Post Office to Addressee" Service under 37 CFR §1.10 on the date indicated above and is addressed to: Mail Stop Petitions, Commissioner for Patents, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA, 22313-1450.

Stephanie Seidman

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Manuel Vega *et al.* Art Unit : 1631
Serial No. : 10/022,249 Examiner : Lin, Jerry
Filed : December 17, 2001 Customer No.: 20985
Conf No. : 7196
Title : **HIGH THROUGHPUT DIRECTED EVOLUTION BY RATIONAL MUTAGENESIS**

MAIL STOP PETITIONS
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

PETITION PURSUANT TO 37 C.F.R. §1.181 FOR RECONSIDERATION AND REMOVAL OF THE FINALITY OF THE OFFICE ACTION

Dear Sir:

Applicant hereby submits a Petition pursuant to 37 C.F.R. §1.181 for reconsideration and removal of the finality of the Office Action, mailed May 9, 2007, in connection with the above-captioned application. This Petition is filed within two months of the mailing of the final rejection.

Remarks begin on page 2 of this paper.

CERTIFICATE OF MAILING BY "EXPRESS MAIL"
"Express Mail" Mailing Label Number: EV 740125484 US
Date of Deposit: **May 25, 2007**
I hereby certify that this paper is being deposited with the United States Postal "Express Mail Post Office to Addressee" Service under 37 CFR §1.10 on the date indicated above and is addressed to: Petitions, Commissioner for Patents, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA, 22313-1450.

Stephanie Seidman

REMARKS

A check for the requisite fee for filing this Petition is attached. Any fees that may be due in connection with the filing of this paper or with this application may be charged to Deposit Account No. 06-1050. If a Petition for Extension of Time is needed, this paper is to be considered such Petition.

It respectfully is submitted that the Final Office Action, mailed May 9, 2007, introduces a new ground of rejection under 35 U.S.C. §103(a) that could have been applied in a previous Office Action. Hence, it was not necessitated by amendment. Therefore, the Action should not have been made Final.

In the instant Office Action, the Examiner has newly rejected claims 1-3, 5, 6, 8-10, 12, 14-23, 32 and 33 under 35 U.S.C. §103(a) over Blazquez *et al.* (Antimicrobial Agents and Chemotherapy (1995) 39(1): 145-149) in view of Giver *et al.* (PNAS (1998) 95:12809-12813). The Examiner alleges that Blazquez *et al.* teaches a process where separate sets of nucleic acid molecules are produced, *where all the nucleic acids in the set encode the same modified protein, and where the nucleic acid molecules in each set are produced by changing one codon in the target protein to a pre-selected codon, whereby the nucleic acid molecules in each set encode proteins that differ from the encoded proteins in another set by one amino acid.* The Examiner alleges that the amendment of the claims necessitate the new ground of rejection. Applicant respectfully submits that, to the extent that this ground of rejection is proper, it could have been applied in the previous Office Action to claims then pending.

In the response filed to the previous Office Action, claim 1 was amended to incorporate the limitations of claim 13, which stated the nucleic acid molecules in each set are produced by changing one codon in the target protein to a pre-selected codon, whereby the nucleic acid molecules in each set encode proteins. Claim 2 depends from claim 1, and recites that the set of nucleic acid molecules is individually designed and synthesized. Hence, amended presently pending claim 2 is essentially the same as previously pending claim 13.

In particular, **claim 13** as previously pending recited:

> ***The method of claim 2, wherein the nucleic acid molecules in step (a) are produced by systematically changing each codon in the target protein to a pre-selected codon, whereby the proteins in each set differ from the proteins in another set by one amino acid.***

Claim 1 was amended to include this limitation. Specifically, claim 1 was amended to incorporate the limitation of claim 13 that recites that the nucleic acid molecules in each set are produced by changing one codon in the target protein to a pre-selected codon, whereby the

nucleic acid molecules in each set encode proteins that differ from the encoded proteins in another set by one amino acid. Claim 1 also was amended for clarity as suggested by the Examiner. In particular, claim 1 was amended as follows:

A process for the identification of a protein that differs in a predetermined property from a target protein, comprising:

(a) producing ~~a population of~~ separate sets of nucleic acid molecules that encode modified forms of a target protein, wherein:

the nucleic acid molecules in each set are produced by changing one codon in the target protein to a pre-selected codon, whereby the nucleic acid molecules in each set encode proteins that differ from the encoded proteins in another set by one amino acid; and

all nucleic acid molecules in a set encode the same modified protein;

(b) individually introducing each set of nucleic acid molecules into host cells, wherein:

the host cells are ~~provided as~~ organized in an addressable array; and

the cells of each locus of the addressable array contain the same modified nucleic acid molecule;

(c) expressing the encoded ~~protein~~ proteins, whereby sets of proteins encoded by the nucleic acid molecules are produced, wherein:

all of the encoded proteins in each set have the same modification; and

the proteins in each set differ from the proteins in another set by one amino acid and from the target protein by one amino acid; and

(d) individually screening each set of encoded proteins, whereby one or more proteins that have a predetermined property that differs from the target protein is/are identified, wherein:

each such protein is designated a hit;

each hit contains a mutation designated a hit position; and

the predetermined property is selected from among a chemical, a physical and a biological property of the target protein.

Thus, claim 1 as amended recites the limitation of previously pending claim 13 that the nucleic acid molecules in each set are produced by changing one codon in the target protein to a pre-selected codon, whereby the nucleic acid molecules in each set encode proteins that differ from the encoded proteins in another set by one amino acid.

Claim 2, which depends from claim 1, recites:

> ***The process of claim 1, wherein each set of nucleic acid molecules is individually designed and synthesized.***

Thus, claim 2 as pending is essentially the same as previously pending claim 13.

As noted above, claim 2, as well as claim 1, newly is rejected over Blazquez *et al.* in view of Giver *et al.* because Blazquez *et al.* allegedly teaches a process where separate sets of nucleic acid molecules are produced, where all the nucleic acids in the set encode the same modified protein, and where the nucleic acid molecules in each set are produced by changing

one codon in the target protein to a pre-selected codon, whereby the nucleic acid molecules in each set encode proteins that differ from the encoded proteins in another set by one amino acid. Claim 13 as previously pending depended from claim 2 and recited that the nucleic acid molecules in step (a) of claim 1 are produced by changing each codon in the target protein to a pre-selected codon, whereby the proteins in each set differ from the proteins in another set by one amino acid.

The new ground of rejection is set forth because it allegedly addresses the limitation added to claim 1, and hence dependent claims such as claim 2. This limitation, however, was previously in claim 13. Thus, to the extent this rejection is applied to pending claim 2, previously pending claim 13, which essentially is the same as amended claim 2, could have been so-rejected. Therefore, the new ground of rejection is not necessitated by the amendment, since claim 13 previously could have been so-rejected.

Failure to withdraw the finality of the Office Action denies the Applicant the right to amend the claims, if needed, and/or provide arguments to overcome this new rejection. Therefore, since the newly recited rejection applied to claim 2 under 35 U.S.C. §103(a) was not necessitated by amendment and could have been raised in a previous Office Action, the finality of the Office Action is improper.

* * *

In light of the above remarks, removal of the finality of the Office Action is respectfully requested.

Respectfully submitted,

Stephanie Seidman
Reg. No. 33,779

Attorney Docket No. 17109-002001 / 911
Address all correspondence to: 20985
Stephanie Seidman
Fish & Richardson P.C.
12390 El Camino Real
San Diego, California 92130
Telephone: (858) 678-5070
Facsimile: (202) 626-7796
email: seidman@fr.com